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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/691,423	10/22/2003	Joseph Oneal	APROG.0101	6169

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EXAMINER	
KRISHNAN, GANAPATHY	

ART UNIT	PAPER NUMBER
1623	

DATE MAILED: 09/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/691,423	ONEAL ET AL.	
	Examiner	Art Unit	
	Ganapathy Krishnan	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 June 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The amendment filed 6/7/2006 has been received, entered and carefully considered. The following information provided in the amendment affects the instant application:

1. Claims 1, 5-15 and 17 have been amended.

2. Remarks drawn to rejections under

Claims 1-17 are pending in the case.

The allowability of claims 15-16 indicated in the previous office action has been withdrawn.

The text of those sections of Title 35, U. S. Code not included in this action can be found in a prior Office action.

Specification

The objection to the specification has been overcome by amendment.

Claim Objections

The objections to claims 8 and 15 have been overcome by amendment.

Claim Rejections - 35 USC § 112

Claims 1-14 and 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention has been overcome by amendments to claims 1, 5, 12-14 and 17.

The following new art rejections are made of record.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-10 and 15-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Wright (Alternative Medicine, Townsend Letter for Doctors & Patients, July, 1999, pages 2-3).

Wright teaches the use of D-Mannose for the treatment of urinary tract infections (page 2, Middle, first paragraph under the title U-TRACT #869). The dosage is one teaspoon in the form of a powder, with meals, three times daily. Each serving contains 1900mg of D-mannose (page 2, paragraph 2 and serving size below third paragraph) and the total number of servings is 26. This works out to about 8 days. This meets the limitations of instant claims 1-3.

Wright teaches administration of d-mannose capsule further comprising pollen extract, extract of Crataeva nurvala and willow bark (page 3, lines 1-9). The dosage of D-mannose in the capsule is 2000mg (page 3, line 11). This teaching is seen to meet the limitations of claims 4-10. The capsule taught by Wright, comprising D-mannose, pollen extract and extracts of Crataeva nurvala and willow bark is a composition, which meets the limitations of claims 15-16.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 11-14 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wright (Alternative Medicine, Townsend Letter for Doctors & Patients, July, 1999, pages 2-3) in combination with Carella et al (WO 97/29763) and Iwahi et al (J. Med. Microbiol., 1982, 15(3), 303-316).

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Wright teaches the use of D-Mannose for the treatment of urinary tract infections (page 2, Middle, first paragraph under the title U-TRACT #869). The dosage is one teaspoon in the form of a powder, with meals, three times daily. Each serving contains 1900mg of D-mannose (page

2, paragraph 2 and serving size below third paragraph) and the total number of servings is 26. This works out to about 8 days.

Wright teaches administration of d-mannose capsule further comprising pollen extract, extract of Crataeva nurvala and willow bark (page 3, lines 1-9). The dosage of D-mannose in the capsule is 2000mg (page 3, line 11). The capsule taught by Wright, comprising D-mannose, pollen extract and extracts of Crataeva nurvala and willow bark is a composition. However, Wright does not teach the specific dosages of the active agents as instantly claimed.

Carella et al teach the use of D-mannose in a composition for the promotion of a healthy environment in urogenital tracts and for treating urogenital disorders (page 2, lines 7-10 and 16-17; page 5, lines 15-16). Plant extracts (interpreted as herbs that affect urinary tract, as instantly claimed in claim 5) are also included in the composition (page 8, lines 23-27). The compositions can be administered as tablets, capsules (page 10, lines 7-10) and can contain 5 to about 75% per unit dose (page 6, lines 22-25). According to Carella additional ingredients and dosages can be readily ascertained using routine experimentation (page 14, lines 32-35). This means that the art recognizes that the dosages can be varied or frequency of administration adjusted till symptoms subside.

Iwahi et al teach that d-mannose is potent in inhibiting viral adhesion to the urinary tract (Abstract).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to administer d-mannose containing the herbal extracts as instantly claimed, to treat urinary tract infection since the use of mannose and the said herbal extracts for the said treatment is seen to be taught in the prior art. One or ordinary skill in the art would be motivated to use d-

mannose and pollen extract and extracts of crataeva nurvala and willow bark as the active agents since d-mannose is potent in preventing viral adhesions to the urinary tract as taught by Iwahi et al and the extracts of pollen, crataeva nurvala and willow bark have additional benefits as taught by Wright (page 3, lines 1-7).

Response to Applicants Arguments

Claims 1-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Benedict et al (US 6,753,319) in combination with Carella et al (WO 97/29763) and Iwahi et al (J. Med. Microbiol., 1982, 15(3), 303-316) is being maintained for reasons of record.

Applicants' argue that:

1. Benedict fails to teach administration three times a day with meals for a period of at least one week and not more than two weeks.

2. Carella also fails to teach administration three times a day with meals for a period of at least one week and not more than two weeks.

3. Both Carella and Benedict do not suggest oral administration and administration in the form of a powder.

Applicants' arguments are found to be persuasive.

Benedict may not teach the dosage and frequency of administration as instantly claimed. But Carella teaches that the compositions of his invention can be administered as tablets, capsules (page 10, lines 7-10) and can contain 5 to about 75% per unit dose (page 6, lines 22-25). According to Carella additional ingredients and dosages can be readily ascertained using routine experimentation (page 14, lines 32-35). Capsules and tablets are administered orally and it is

well known that capsules can contain the active agents in the form of a powder. Hence, one of ordinary skill in the art will recognize that the active agents can be administered orally in the form of a powder.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988 and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992).

Conclusion

Claims 1-17 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ganapathy Krishnan whose telephone number is 571-272-0654. The examiner can normally be reached on 8.30am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

GK

8/30/06

Shaojia Jiang
Supervisory Patent Examiner
Art Unit 1623